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FOREWORD


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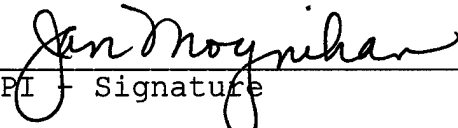
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INTRODUCTION

The diagnosis of breast cancer is, obviously, a major life stressor for a woman, her family, and friends. This extreme psychological distress in the patient can, in turn, have consequences for both immune function and disease pathogenesis. As an appropriate example, stress can decrease the function of natural killer (NK) cells, which can lyse virally-infected and tumor cells (1-4). A small, but compelling literature indicates that the administration of a psychosocial intervention to stressed populations, including geriatric patients (5), malignant melanoma patients (6-8), and HIV positive individuals (9), can result in increased NK cell cytotoxicity. The effects of intervention on NK cell activity in breast cancer patients have not been fully examined; an exploratory study indicates that intervention following breast cancer surgery is beneficial (10). Further, no intervention studies have been conducted during the interval between diagnosis and surgery, when, as discussed in the next section, it is advantageous for patients to be in the best possible immunological state.

The literature on the effects of psychosocial intervention on psychological well-being is similarly compelling but undeveloped. Structured support groups and intervention therapies can improve the psychological well-being of breast cancer patients (10-16) and even increase length of survival in advanced metastatic breast cancer patients (16,17) and stage I and II melanoma patients (6,8). While there is a small literature on presurgical educational interventions (18,19), the overwhelming majority of psychosocial intervention studies have, unfortunately, been initiated postsurgically.

Outcome measures used in most psychosocial studies of cancer patients have been relatively narrow and typically focused on anxiety, depression, or other negative affects. There is some suggestion that women with no prior psychiatric history appear to recover from their perioperative distress approximately one year after surgery (20,21). Yet decreased well-being may be evident in other ways, including increased somatic complaints and unnecessary healthcare utilization. A presurgical psychosocial intervention may enhance psychological well-being, as measured by an increase in self-perceived health, decrease in somatic complaints, and a decrease in healthcare utilization.

There are two main reasons for safeguarding immunity in the perioperative period. First, there is a risk of infection associated with all surgical procedures, as well as other iatrogenic infection. Second, surgery is associated--in animal models--with an increase in experimentally-induced or spontaneous metastases (22-24), which is an important consideration for women with metastases or micrometastases. That is, surgery for breast cancer might result in an accelerated development of metastases present before or during surgery. Thus, it is highly adaptive to patients awaiting surgery to be in the best possible immunological state.

BODY

Hypothesis/Study Purpose

Women awaiting breast cancer surgery are distressed and anxious. This stressful state may lead to the decreased immune function observed during the interval (typically, 1-3 weeks) between breast cancer diagnosis and surgery. No published research has investigated whether a psychosocial intervention can affect immune function in breast cancer patients, nor has any intervention study been designed to alter the immunological state of the subjects at a time when they are at risk for development of secondary infection or metastases. We hypothesize that a structured psychosocial intervention administered prior to surgery will minimize the decline in immune function prior to--and as a result of--surgery. However, we expect that patients receiving intervention will still have some degree of surgery-induced suppression of NK cell function.

A presurgical psychosocial intervention may also affect numerous indicators of psychiatric and physical morbidity, and have an impact on healthcare costs. We are testing this hypothesis by collecting data on depression, somatic complaints, healthcare utilization, and self-perceived health at six months following surgery. We are also determining whether the groups differ in immune

function at six months, exploring differences in self-reported infectious illness, and tracking the development of chart-documented metastases.

Technical Objectives

In a population of women recently diagnosed with breast cancer, we are:

1. Determining if a psychosocial intervention affects immune function measured one or two days prior to surgery and one week following surgery.
2. Determining if a psychosocial intervention affects immune function, psychological well-being, and psychosocial function six months following surgery.

Methods

Overview of experimental design. A pretest-posttest control group design is used (25). Breast cancer patients are recruited from four local sites. In the first six months of recruitment, all patients were assigned to the intervention group to pilot the intervention. Since then, using the method of restricted randomization, patients are randomly assigned to either a control group (standard care) or an experimental group (standard care plus psychosocial intervention). Psychological and immunological assessments are conducted at four timepoints:

- Time 1) prior to intervention;
- Time 2) post-intervention, one-two days prior to surgery;
- Time 3) one week following surgery; and
- Time 4) six months following surgery.

In addition to establishing pre-randomization immunological status, these data ensure that the two groups do not differ in the outcome variables at study entry. Although we have considered conducting psychological and immunological assessments on the morning of surgery, clinical considerations led us to opt for Time 2 data collection one-two days before surgery. At Time 2, we expect that the intervention should have an impact on immune function. Time 3 data reflects potential differences in immune function as a function of intervention superimposed upon immune changes due to surgical stress. Data collection at six months (Time 4) will enable us to examine whether the intervention decreased psychiatric morbidity and explore whether there are immunological differences. As well, this timepoint should establish baselines for NK cell function and cytokine levels in the control subjects (26). These values are expected to have returned to levels observed in normal healthy controls, with the exception of those patients receiving additional therapy.

Subjects and recruitment sites. Breast cancer patients are recruited from four sites: the surgery practices of: Carl Andrus, M.D., Clinical Associate Professor in Surgery at the University of Rochester; James Peacock, M.D., Associate Professor in Surgery at the University of Rochester; and Chris Caldwell, M.D., Clinical Assistant Professor in Surgery at the University of Rochester. In addition, we recruit patients from the radiology practice of Wende Logan-Young, M.D., Clinical Professor in Radiology, University of Rochester. Drs. Peacock and Andrus practice at the Strong Memorial Hospital of the University of Rochester, and Dr. Andrus also performs surgery at an off-site surgicenter. Dr. Caldwell performs surgery at the Genesee Hospital. Dr. Logan-Young's Elizabeth Wende Breast Clinic is also off-site. Thus, we are accruing patients from a variety of locations in Rochester, and these patients often come from a great distance, particularly in the case of Dr. Logan-Young. We recognize that there still may be limitations to the generalizability of findings from the proposed sites of subject recruitment. The proposed sample is appropriate at this stage of scientific development and may lay the groundwork for a more elaborate study in the future. We also recognize that subjects who agree to participate may be medically and psychologically different from those who refuse, but this issue will, by necessity, remain unexamined.

Exclusion criteria are as follows. Patients for whom surgery has been scheduled within one week of diagnosis are excluded because there is insufficient time for the intervention. Other exclusion criteria have been developed to clarify the interpretation of the immunological data. We exclude women who are pregnant or have recently given birth, those who have reported an

infectious illness within the past two weeks, and patients who are taking medications with any obvious immunological or endocrinological consequences (27,28).

Immune Measures. PBMC are isolated from 30 ml of diluted, heparinized blood by centrifugation over Ficoll-Hypaque (Pharmacia, Piscataway, NJ). PBMC at the interface will be washed twice, counted, and resuspended to $5-10 \times 10^6$ cells/ml in fetal bovine serum (FBS). In order to assess immune function in PBMC from all four study time points together, cells are frozen at -80°C according to the protocol of Vingerhoets et al. (29). At the time of assay, aliquots of cells will be washed twice and resuspended to 10^7 cells/ml in RPMI 1640 containing 10% FBS, 2 mM L-glutamine, 50 μM 2-mercaptoethanol, 25 mM HEPES, 100 U/ml penicillin, and 100 $\mu\text{g}/\text{ml}$ streptomycin sulfate (complete RPMI, all reagents from GIBCO, Grand Island, NY).

Natural killer cell activity. A standard ^{51}Cr release assay using the K562 cell line (ATCC, Rockville, MD) will be used to measure NK cell (30). Effector cells will be mixed in complete RPMI with ^{51}Cr -labeled targets cells at effector:target (E:T) cell ratios of 100:1, 50:1, 25:1, 12.5:1, and 6.25:1. Supernatants will be harvested following a 4 hr incubation in 5% CO_2 at 37°C . Statistical analysis will be performed on the percent specific lysis for all six E:T cell ratios. Lytic units at 30% lysis will also be determined according to the method of Pross et al. (31).

Cytokine production. PBMC at optimal cell concentrations to be determined (approximately $1-10 \times 10^7$ cells/ml) will be cultured with 1 and 10 $\mu\text{g}/\text{ml}$ phytohemagglutinin (PHA, Sigma Chemical Co., St. Louis, MO). Supernatants will be harvested at 24, 48, and 72 hr and assayed for the cytokines IL-2 and IFN- γ using a standard ELISA protocol and anti-cytokine antibody pairs (PharMingen, San Diego, CA). We currently use the equivalent reagents for murine cytokines in ELISA assays in our lab (32,33).

Psychological measures. Data on the following demographic and background measures are collected: age; marital status; number of children; education; race; employment status; income; and insurance coverage. The psychological measures include:

1. CES-D, a 20-item measure of depression that places relatively less emphasis on physical symptoms (34).
2. Life Orientation Test, an 8-item measure of global optimism previously used in research on breast cancer patients (35), is used as a predictor of outcome in secondary analyses.
3. Physical and functional status is measured using the SF-36, a widely used instrument derived from the Medical Outcome Study (36).
4. While not a focus of the present study, questions about religious beliefs (37), social support (38), and the presence of other adverse life events are asked because these variables have consistently been related to psychological adjustment. Their influence on immune outcome measures will be examined in secondary analyses.
5. Using the methods described by Orts et al. (28), self-reported infections are recorded at two, four, and six months post-surgery.
6. Chart-documented metastases are recorded, but it is unlikely that they will be present in sufficient numbers of patients to warrant analysis.

Copies of each of the questionnaires are included with this report as **Appendix 1**.

As a manipulation check, the subjects in both groups are asked if they have received any psychological counseling or individual and group psychotherapy, apart from that received in the study. The attendance of subjects in the intervention group is monitored, as is the self-reported frequency with which they engage in intervention-related activities such as relaxation. A series of questions is asked concerning the following "lifestyle variables" which may confound the immune assessment: sleep; alcohol and caffeine consumption; current smoking habits; and diet. As a result of randomization, the groups should not differ at Time 1 on age, education, lifestyle variables, or disease variables (tumor type and staging); the interval between diagnosis and surgery; or the number of patients receiving chemotherapy following surgery.

e) **Procedure.** The physicians screen patients for eligibility. After informing eligible patients of a breast cancer diagnosis, the physicians acquaint them with this study, provide them with a copy of our study brochure (**Appendix 2**), and ask if they would be willing to be contacted by our Health Project Coordinator. Those who agree, are contacted within two days and provided with further information and formally asked to participate. After providing informed consent (**Appendix 3**),

the subjects complete the preintervention psychological assessment and have their blood drawn (Time 1). Results of the randomization are provided shortly thereafter. Patients in the experimental group begin the group treatment intervention as soon as possible (within three-five days of recruitment). The Health Project Coordinator telephones all subjects at two months and four months following surgery to collect data regarding infections. It is expected that this contact decreases attrition at six months, when blood is drawn, psychological data collected, and infectious illness again assessed.

f). Intervention. Patients attend two treatment sessions, held on Tuesdays, Wednesdays, or Fridays. The number of patients in each group varies according to recruitment and randomization. The intervention design is consistent with findings and recommendations from previous treatment research with cancer patients (6-8), indicating that newly diagnosed and early treatment stage patients are responsive to highly structured group interventions. The objectives of the 90 minute intervention sessions are as follows:

1. To teach and practice relaxation techniques and stress management aimed at identifying and alleviating stress;
2. To improve problem-solving skills required for effective crisis management (e.g., taking an active versus a passive approach to problem solving; establishing priorities; actively and openly communicating concerns to practitioners, family and friends);
3. To offer psychosocial support through group discussion and sharing about specific problems and concerns commonly faced by breast cancer patients; and
4. To increase health education about means of improving and maintaining good health habits.

An outline of the intervention group is included as **Appendix 4**.

The intervention group is an open group, with new members present at each session. The group has been led by Nancy Talbot, Ph.D. or Nancy Cooper, Ph.D., both clinical psychologists with appointments in the Department of Psychiatry. The group sessions are held in a comfortable conference room in the Department of Psychiatry.

Statistical analysis. Data analyses is being conducted in consultation with Christopher Cox, Ph.D., primarily using SAS and BMDP. Immune outcome variables are NK cell function, IFN- γ , and IL-2 production derived from multiple measurements. Measurements from the two groups will be compared using repeated measures analysis of variance (ANOVA). The between factor for these analyses will be group. The within factor will be the dilution level of the assay. Post treatment values of all outcome variables will be adjusted for preintervention levels by subtraction. Each analysis will use the Greenhouse-Geisser adjustment for degrees of freedom and will include an examination of residuals as a check on the assumptions of normally distributed errors with constant variance. Secondary analyses discussed under "Psychological Measures" will also be conducted.

Technical Objective 1. Repeated measures ANOVA will be used to test the hypothesis that the groups will differ in NK cell function and cytokine production on the day of the presurgery physical, as well as one week following surgery.

Technical Objective 2. ANOVA will be used to test the hypothesis that the groups will differ at the six month follow-up in: depression (CES-D); somatic complaints; self-perceived health (SF-36); and healthcare utilization. Repeated measures ANOVA will be used to examine differences in immune function.

Obstacles/problems with performance of this study during the initial year and solutions to these problems.

This breast cancer study, which proposes to correlate psychological well-being with immunological well-being, should provide us with important new data for determining appropriate and efficacious psychological treatments for cancer patients. In addition, during the first year of funding, it has presented all of the study members with a wide variety of clinical issues and problems to solve. Entering the second year of funding, we have gained perspective in how best to conduct intervention studies, and we will use this considerable information in completing this study and in designing all of our future clinical studies.

1. The need for a full-time study coordinator/phlebotomist.

The budget for this proposal requested salary money for a half-time (20 hr/week) Health Project Coordinator (HPC). In August 1996, Kathy Chiavaroli was hired for this position. The PI and co-PI quickly observed, however, that the rigid time restrictions of this half-time HPC did not fit the needs of the study. That is, an unacceptable number of patients were not recruited into the study because the HPC was not available at those times or did not know that the patients were being seen by our referring physicians. In addition, procuring blood from our patients at each of our four sites was problematic. To make study participation by patients as easy as possible, we determined that the HPC should also be a certified phlebotomist who could easily perform venipuncture. Our strategy was to seek additional internal funding from the University of Rochester Center for Psychoneuroimmunology Research to obtain salary support to hire a full-time HPC/Clinical Technologist. We received \$15,000 toward salary and benefits, and began recruitment of this individual. Unfortunately, before we could legally recruit a full-time study coordinator, we were forced to terminate our half-time coordinator. Thus, we did not recruit any new patients between March-June 1997. In late June 1997, we hired Heather Frazer, a full time study coordinator/phlebotomist with a flexible schedule. We are now actively recruiting patients again. During the summer of 1997, we are aided by the efforts of Tanya Weissman, a third year medical student at the University of Rochester. Ms. Weissman has become the liaison between the laboratory and the offices of Dr. Wende Logan-Young, our referring radiologist.

2. An apparent decrease in the number of breast cancers diagnosed by our referring physicians.

Wende Logan-Young, M.D. diagnoses approximately 400 cases of breast cancer each year, and our referring surgeons estimated that they were seeing 10-15 new breast cancer patients each week. Applying the exclusion criteria to this figure yielded an eligible sample of 8-12 patients per week. Dr. Duberstein's prospective study of lung cancer patients and their spouses, recruited from surgeons' offices, has yielded a participation rate of approximately 70%. Thus, we anticipated recruiting 5-8 newly diagnosed patients per week. In fact, during the period from October 1996-February 1997, only 32 patients were referred to us. An examination of the operating room log for Strong Memorial Hospital showed that the number of breast cancer surgeries decreased by 20% from mid-1996 to mid-1997. Thus, at least at Strong Memorial Hospital, where two of our three surgeons practice, the number of surgeries is down. To deal with this apparent decrease in cases of breast cancer, we increased our recruitment sites to include Genesee Hospital. If necessary, we will also include surgeons at Rochester General Hospital.

We do not know if this observed decrease in new breast cancer cases is spurious or reflects a trend for patients to have surgery at other area hospitals. In fact, we speculate that many women may be choosing to have surgery at the Highland Hospital because of Highland's new and growing Women's Health Center, which offers numerous alternative therapies (i.e., massage therapy, aromatherapy, group support, etc.) to patients, in addition to standard medical care. The "unfortunate" aspect of the growth of such programs is that it will become difficult to evaluate the efficacy of interventions in a controlled, scientific fashion because of a lack of adequate control subjects. As **Appendix 5**, we include the growing list of area support groups available to women with breast cancer, which we ethically make available to women should they request such information.

3. Patients declined to participate in the study for a number of reasons.

Of the 32 patients who were referred to us between October-February, only 10 patients agreed to participate (31.25%). A number of reasons were given for declining our invitation to participate, including: lack of interest; too busy with other things; a sense of support from religion and family precluding the need for intervention; distance from the group meeting being too great; and the intervention group meeting time being inconvenient. Of these reasons, we are able to address only the last two. In September of 1997, we will be joined by Mark Larson, Ph.D., a clinical psychologist who will be a postdoctoral fellow in the Center for Psychoneuroimmunology Research. Dr. Larson's schedule will allow him to conduct intervention groups on a more flexible basis, and even to see patients off-site, if necessary. We anticipate that we will be able to recruit significantly more patients with Dr. Larson as a collaborator.

The obstacles we have encountered have been considerable; however, we have made great progress in restructuring the study to make the technical objectives approachable. We are concerned, however, that we will not complete this important study in the contracted time of two years, and would like to explore with the DOD the possibility of an extension of this study.

CONCLUSIONS

The immunological and psychological data that we are collecting will be analyzed during the final six months of this study, which is likely to be delayed due to the unanticipated rate of subject recruitment. To date, we have collected demographics from our study population as shown in Table 1.

Table 1. Demographics from 10 study participants October 1996-February 1997

Age (in years): <50: 2 50 - 55: 1 56 - 60: 5 >60: 2 average age= 56.4 yrs Race: Caucasian: 10 Marital Status: married, living with spouse: 8 divorced: 1 widowed: 1 Employment: full time: 6 part time: 1 retired: 3 Education: high school: 1 some college: 2 AAS: 2 BA: 2 MA: 2 unknown: 1 Income: \$35,000 - \$50,000: 2 \$50,000 - \$75,000: 4 \$75,000 - \$100,000: 1 \$100,000 +: 3	Health Insurance: BC/CS, Pref. Care, Bch: 8 private insurer: 1 Medicaid: 1 Religious affiliation: Protestant: 9 Catholic: 1 Practice Religion: yes: 6 no: 4 Learned of diagnosis from: Radiologist: 9 Physician at Breast Cancer clinic: 1 Time elapsed between diagnosis and recruitment (in days): < 10: 3 10 - 25: 5 26 - 40: 1 >40: 1 average time = 16.7 days
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In addition, we have analyzed the data from the CES-D depression scale administered to patients at the time of recruitment into the study (Time 1). Although our sample size is small, a 1-tailed t-test indicates that our patients (mean CES-D score=12.22) have significantly higher (indicating higher levels of symptoms) scores than the age- and sex-matched control population (mean score=8.67) ($p<.05$). We do not have sufficient data yet from our intervention and control group breast cancer patients to evaluate the effects of intervention on psychological well-being.

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APPENDIX I

<u>Form #</u>	<u>Visit</u>	<u>Name</u>	<u>Description</u>
001	Index only	Admission Dataform	demographics
002	Index, 1, 2, + 3 follow-up	CES-D	measure of depression
003	Index, 1, 2, + 3 follow-up	Life Orientation Scale	measure of global optimism
004	Index, 1, 2, + 3 follow-up	SF-36 Health Status Survey	measure of physical and functional status
006	Index only	Short Life Events Profile	deaths of loved ones in the past 5 years
007	Index only	Medical History Dataform	
008	A- Index B- 1, 2, 3, + follow-up	DES-IV (A + B)	measure of emotions since diagnosis of cancer
009	A- Index B- 1, 2, 3, + follow-up	Impact of Events (A + B)	measure of stress after diagnosis of cancer
011	Index, 1, 2, + 3 follow-up	Health Behaviors (PSQI)	examines lifestyle variables
015	2+3 follow-up	Disease Status	
016	Index	Social Network and Support Assessment	measures social support
018	after 1+2 intervention	Intervention Inventory	measures helpfulness of interventions

ADMISSION DATAFORM

For Office Use Only

Form: 0 0 1 (1)
Study Code: (4)
Patient ID #: (6)
Today's Date (mm/dd/yyyy): / / (11)

1. What is your gender?

1. Male 2. Female

2. What is your date of birth?

(mm/dd/yyyy) / /

3. Of what race do you consider yourself? (circle one)

1. White
2. American Indian, Eskimo, Aleut
3. Other Race
4. Black (African American)
5. Asian or Pacific Islander
6. Mixed Race

4. Do you consider yourself of Hispanic origin? (circle one)

1. Yes 2. No

5. What is your marital status? (circle one)

1. Married, living with spouse
2. Married, not living with spouse
3. Divorced
4. Legally separated
5. Widowed

6. With whom do you live?(circle one)

1. Alone
2. Married, living with spouse
3. Married, not living with spouse
4. Legally separated
5. Divorced
6. Widowed

7. How many children do you have?(circle one)

1. None
2. One
3. Two
4. Three
5. Four or more

OFFICE USE ONLY

 (19)

 (20)

 (28)

 (29)

 (30)

 (31)

 (32)

8. What is your employment status? (circle the one that BEST applies)

- 01. Full-time employment
- 02. Part-time employment
- 03. Retired
- 04. Retired from full- time employment, currently working for pay
- 05. On Disability
- 06. Unemployed
- 07. Full/part-time student
- 08. Full-time homemaker

9. If retired, how long has it been since you retired? (circle one)

- 01. 0-1 years
- 02. 1-2 years
- 03. 2-5 years
- 04. 5 or more years
- 88. Not retired/Not applicable

What is/was your occupation? _____

10. How far did you go in school? (Circle one)

- 01. Less than 9 years
- 02. Did not finish high school
- 03. Finished/graduated high school
- 04. Some college/technical school
- 05. College graduate
- 06. Masters degree
- 07. Doctorate of professional (PhD, MD, DO, DDS, JD)

11. What was your household's total income last year, before taxes? (This includes wages, social security, pensions, and interest or dividends on savings and investments.)

- 01. Less than \$10,000
- 02. Between \$10,000 and \$25,000
- 03. Between \$25,000 and \$35,000
- 04. Between \$35,000 and \$50,000
- 05. Between \$50,000 and \$75,000
- 06. Between \$75,000 and \$100,000
- 07. More than \$100,000

12. What type of health insurance pays a majority of your medical bills?

- | | |
|----------------------------|---------------------|
| 01. Medicare | 04. Medicaid |
| 02. Blue Cross/Blue Shield | 05. Private insurer |
| Pref. Care, Blue Choice | 06. Self pay |
| 03. HMO | 07. No insurance |

____ (33)

____ (35)

____ (37)

____ (39)

____ (41)

Patient ID #: _____

Admission Dataform - Page 3/3

13. In what religion/denomination were you raised?

- | | |
|----------------|-------------------------|
| 01. Catholic | 05. Mormon |
| 02. Protestant | 06. Hindu |
| 03. Jewish | 07. Buddhist |
| 04. Muslim | 08. None/Not applicable |
| | 09. Other: _____ |

14. Do you currently practice a particular religion?

1. Yes 2. No

15. Who told you that you have breast cancer?

01. Ob/Gyn
02. Internist/Family doctor
03. Radiologist
04. Surgeon
05. Other _____

16. When were you told you have breast cancer?

____ / ____ / _____

____ (43)

____ (45)

____ (46)

____ / ____ / ____ (48)

CES-D

Form:		FOR OFFICE USE ONLY	
Patient's I.D. #		0	0 2 (1)
Today's Date: (mm/dd/yyyy)			(4)
Visit: 0=Index	2=2nd follow up		(9)
1=1st follow up	3=3rd follow up		(17)

Instructions: For each of the following statements, please circle the response that best describes how you felt more days than not in the last week. Please do not write in the grey shaded areas. Please complete each question of this survey.

	<u>Rarely or</u> none of the time	<u>Some of</u> the time	<u>Much of</u> the time	<u>Most or</u> all of time
1) I was bothered by things that usually don't bother me	0	1	2	3
2) I did not feel like eating, my appetite was poor	0	1	2	3
3) I felt that I could not shake off the blues even with help from my family and friends	0	1	2	3
4) I felt that I was just as good as other people	0	1	2	3
5) I had trouble keeping my mind on what I was doing	0	1	2	3
6) I felt depressed	0	1	2	3

FOR OFFICE USE ONLY	
	(18)
	(19)
	(20)
	(21)
	(22)
	(23)

Continued on back of this page

CES-D

Patient's I.D. _____

Page 2/2

Describe how you felt more days than not in the last week.

		Rarely or none of the time	Some of the time	Much of the time	Most or all of time
7)	I felt that everything I did was an effort	0	1	2	3
8)	I felt hopeful about the future	0	1	2	3
9)	I thought my life had been a failure	0	1	2	3
10)	I felt fearful	0	1	2	3
11)	My sleep was restless	0	1	2	3
12)	I was happy	0	1	2	3
13)	It seemed that I talked less than usual	0	1	2	3
14)	I felt lonely	0	1	2	3
15)	People were unfriendly	0	1	2	3
16)	I enjoyed life	0	1	2	3
17)	I had crying spells	0	1	2	3
18)	I felt sad	0	1	2	3
19)	I felt that people disliked me	0	1	2	3
20)	I could not get going	0	1	2	3

____ (24)

____ (25)

____ (26)

____ (27)

____ (28)

____ (29)

____ (30)

____ (31)

____ (32)

____ (33)

____ (34)

____ (35)

____ (36)

____ (37)

LIFE ORIENTATION SCALE

Form:		FOR OFFICE USE ONLY	
Patient's I.D. #		0	0 3 (1)
Today's Date: (mm/dd/yyyy)			(4)
Visit: 0=Index	2=2nd follow up		
1=1st follow up	3=3rd follow up		(9)
			(17)

Instructions: Please indicate how strongly you agree or disagree with each statement. Circle the appropriate response.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	FOR OFFICE USE ONLY
1) In uncertain times, I usually expect the best.....	SA	A	N	D	SD	(18)
2) If something can go wrong for me, it will.....	SA	A	N	D	SD	(20)
3) I always look on the bright side of things.....	SA	A	N	D	SD	(22)
4) I am always optimistic about my future.....	SA	A	N	D	SD	(24)
5) I hardly ever expect things to go my way.....	SA	A	N	D	SD	(26)
6) Things never work out the way I want them to.....	SA	A	N	D	SD	(28)
7) I am a believer in the idea that "every cloud has a silver lining"	SA	A	N	D	SD	(30)
8) I rarely count on good things happening to me.....	SA	A	N	D	SD	(32)

SF-36™ HEALTH STATUS SURVEY

Form:		FOR OFFICE USE ONLY	
Patient's Name I.D.#		0	0 4 (1)
Today's Date: (mm/dd/yyyy)			(4)
Visit: 0=Index	2=2nd follow up		(9)
1=1st follow up	3=3rd follow up		(17)

Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer every question by circling the appropriate number. If you are unsure about how to answer a question, give the best answer you can. Please complete all questions on this survey.

1. In general, would you say your health is:

1 Excellent	4 Fair
2 Very good	5 Poor
3 Good	
2. Compared to one year ago, how would you rate your health in general now?

1 Much better now than 1 year ago
2 Somewhat better now than 1 year ago
3 About the same
4 Somewhat worse now than 1 year ago
5 Much worse now than 1 year ago

FOR OFFICE USE ONLY	
	(18)
	(19)

Continued on back of this page

The following items are about activities you might do during a typical day.
 Does your health now limit you in these activities? If so, how much?
 (Circle one number on each line.)

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All	
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3	(20)
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3	(21)
5. Lifting or carrying groceries	1	2	3	(22)
6. Climbing several flights of stairs	1	2	3	(23)
7. Climbing one flight of stairs	1	2	3	(24)
8. Bending, kneeling, or stooping	1	2	3	(25)
9. Walking more than a mile	1	2	3	(26)
10. Walking several blocks	1	2	3	(27)
11. Walking one block	1	2	3	(28)
12. Bathing or dressing yourself	1	2	3	(29)

FOR OFFICE
USE ONLY

SF-36

Patient's I.D.# _____

Page 3/5

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number on each line.)

- | | Yes | No |
|--|-----|----|
| 13. Cut down the <u>amount of time</u> you spent on work or other activities | 1 | 2 |
| 14. <u>Accomplished less</u> than you would like | 1 | 2 |
| 15. Were limited in the <u>kind</u> of work or other activities | 1 | 2 |
| 16. Had difficulty performing the work or other activities (for example, it took extra effort) | 1 | 2 |

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?
(Circle one number on each line.)

- | | Yes | No |
|---|-----|----|
| 17. Cut down the <u>amount of time</u> you spent on work or other activities? | 1 | 2 |
| 18. <u>Accomplished less</u> than you would like? | 1 | 2 |
| 19. Didn't do work or other activities as <u>carefully</u> as usual? | 1 | 2 |

Continued on back of this page

FOR OFFICE
USE ONLY

____ (30)

____ (31)

____ (32)

____ (33)

____ (34)

____ (35)

____ (36)

20. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number.)
- | | |
|--------------|---------------|
| 1 Not at all | 4 Quite a bit |
| 2 Slightly | 5 Extremely |
| 3 Moderately | |
21. How much bodily pain have you had during the past four weeks? (Circle one number.)
- | | |
|-------------|---------------|
| 1 None | 4 Moderate |
| 2 Very mild | 5 Severe |
| 3 Mild | 6 Very severe |
22. During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number.)
- | | |
|----------------|---------------|
| 1 Not at all | 4 Quite a bit |
| 2 A little bit | 5 Extremely |
| 3 Moderately | |
23. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)
- | |
|------------------------|
| 1 All of the time |
| 2 Most of the time |
| 3 Some of the time |
| 4 A little of the time |
| 5 None of the time |

_____ (37)
_____ (38)
_____ (39)
_____ (40)

Please choose the answer that best describes how true or false each of the following statements is for you.
(Circle one number on each line.)

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
24. I seem to get sick a little easier than other people.	1	2	3	4	5
25. I am as healthy as anybody I know.	1	2	3	4	5
26. I expect my health to get worse.	1	2	3	4	5
27. My health is excellent.	1	2	3	4	5

_____ (41)
_____ (42)
_____ (43)
_____ (44)

SHORT LIFE EVENTS PROFILE

Form: _____ 0 0 6 (1)
 Patient's I.D. # _____ (4)
 Today's Date: (mm/dd/yyyy) _____ / _____ / _____ (9)
 Visit: 0=Index 2=2nd follow up
 1=1st follow up 3=3rd follow up _____ (17)

For questions 1-7 code the absence or presence of each of the following for the last five years only. If absent, code "A". If present, use the following key to code date of death. If the time period falls between categories, code the higher time frame. (e.g. 5.5 weeks = 2) If there was more than one occurrence, code the date of the most recent.

Codes: A= Absent 3= 14-26 weeks 6= 2-3 years
 1= 0-5 weeks 4= 27-52 weeks 7= 3-5 years
 2= 6-13 weeks 5= 1-2 years 9= Unknown

- | | |
|--|------------------------|
| 1) Did any of your children die?
If so, how many?
If so, when? | ____ (18)
____ (19) |
| 2) Did either of your parents die?
If so, how many?
If so, when? | ____ (20)
____ (21) |
| 3) Did any of your siblings die?
If so, how many?
If so, when? | ____ (22)
____ (23) |
| 4) Did any other close relatives of <u>subject</u> die?
If so, how many?
If so, when? | ____ (24)
____ (25) |
| 5) Did any close friends of <u>subject's</u> die?
If so, how many?
If so, when? | ____ (26)
____ (27) |
| 6) Was there a life threatening illness diagnosed in your parents, children, or siblings?
(cancer, Alzheimers, etc.)
If so, how many?
If so, when? | ____ (28)
____ (29) |
| 7) Over the last five years, have you cared for a relative or friend who was suffering
from a degenerative condition? (cancer, Alzheimers, Parkinson's)
If so, how many?
If so, when did you start providing care and support? (By "care and support" we
mean instrumental and ADL support, providing transportation, washing, laundry, bathing, etc.) | ____ (30)
____ (31) |

MEDICAL HISTORY DATAFORM

FOR OFFICE USE ONLY

Form: _____ 0 0 7 (1)

Patient's I.D. # _____ (4)

Today's Date: (mm/dd/yyyy) ____ / ____ / ____ (9)

Visit 0=Index 2=2nd follow up
 1=1st follow up 3=3rd follow up _____ (17)

Chronic Conditions and Symptoms (Adapted from Belloc, Breslow and Hochstim 1971)

Code Questions 1-19: 1=Present in the last 12 months

2=Absent in the last 12 months

- | | OFFICE USE |
|---|------------|
| 1) Do you have arthritis or rheumatism? If so, where? | ____ (18) |
| 2) Do you have any problems with your blood pressure? | ____ (19) |
| 3) Have you had a stroke? | ____ (20) |
| 4) Do you have any problems with your heart? | ____ (21) |
| 5) Do you have any other cancer? If so, where? | ____ (22) |
| 6) Do you have epilepsy or a seizure disorder? | ____ (23) |
| 7) Do you have any other neurologic diseases? If so, what? (MS, CP) | ____ (24) |
| 8) Do you have diabetes? | ____ (25) |
| 9) Do you have asthma? | ____ (26) |
| 10) Do you have chronic bronchitis? | ____ (27) |
| 11) Do you have emphysema? | ____ (28) |
| 12) Do you have tuberculosis? | ____ (29) |
| 13) Do you have any problems with your thyroid? If so, what? | ____ (30) |
| 14) Do you have a stomach or duodenal ulcer? | ____ (31) |
| 15) Do you have chronic liver trouble? | ____ (32) |
| 16) Do you have chronic gallbladder trouble? | ____ (33) |
| 17) Do you have a hernia or rupture? | ____ (34) |
| 18) Do you have any hearing problems? If so, what? | ____ (35) |
| 19) Do you have any problems with your vision? If so, what?
(functional impairment, cataracts, trauma, macular degeneration) | ____ (36) |

Patient's I.D. # _____

Which medications (prescription/non-prescription) are you currently taking on a regular basis?

(include vitamins, nasal sprays, aspirin)

- a) _____ d) _____
b) _____ e) _____
c) _____ f) _____

20) Total number of prescription and non-prescription medications (not PRN) taken on a regular basis at time of interview:

____ (37)

21) Have you ever been on any psychotropic medications? 1=Yes 2=No (refer to Q 22-30)
e.g. for your nerves, sadness, depression, (not PRN)

____ (39)

Are you currently taking any of the following psychotropic medications?

(Fixed-dose or PRN) 1=Prescribed/Taking 2=Prescribed/Not Taking 3=Not Prescribed 4=Not Prescribed/Taking

22) Antidepressants

____ (40)

23) Antipsychotic medications

____ (41)

24) Lithium

____ (42)

25) Benzodiazepine or other sedative/hypnotic/anxiolytic (except Buspirone)

____ (43)

26) Anticonvulsant (other than clonazepam)

____ (44)

27) Narcotic Analgesics

____ (45)

"Now I am going to read a list of symptoms. Please tell me if you have experienced any of these in the last year including the last week, in the last year excluding the last week or if you have not experienced them at all in the last year."

1=Present in the last 12 months, excluding the last week;

2=Present in the last 12 months, including the last week;

3=Absent in the last 12 months

Prompt: "more than most people your age"

28) Constant coughing or frequent heavy chest colds

____ (46)

29) Trouble breathing or shortness of breath

____ (47)

30) Getting tired in a short time

____ (48)

31) Frequent headaches

____ (49)

32) Stiffness, swelling, aching or paralysis in any joint or muscle

____ (50)

33) Pain, tightness or heaviness in the heart or chest

____ (51)

34) Pains in the back or spine

____ (52)

35) Repeated pains in the stomach

____ (53)

36) Frequent cramps

____ (54)

37) Swollen ankles

____ (55)

Patient's I.D. # _____

38) Have you ever seen a psychiatrist, counselor, or therapist?

1=Yes

2=No

____(56)

The following questions are related to the levels of hormones that may or may not be in your blood.

39) Have you had a hystserectomy?

1=Yes

2=No

____(57)

40) Are you on birth control pills?

1=Yes

2=No

____(58)

41) Do you have regular periods?

1=Yes

2=No

3=Menopause

4=Don't know

____(59)

42) What was the first day of your last menstrual period?

Menopause or don't know code all 9's

____/____/____(60)

Form:	0 0 8 (1)
Patient's I. D. #	(4)
Today's Date: (mm/dd/yyyy)	(9)
Visit: 0=Index	(17)

Instructions: For each item, circle the number that best answers the question. Please answer every question, and do not write in the grey shaded areas. In responding, consider your emotions since your diagnosis of cancer.

Since your diagnosis of cancer, how often in your daily life do you...

Rarely Hardly Some- Often Very
Ever times times times times

- | | | | | | |
|---|---|---|---|---|---|
| 1. Feel regret, sorry about something you did? | 1 | 2 | 3 | 4 | 5 |
| 2. Feel glad about something? | 1 | 2 | 3 | 4 | 5 |
| 3. Feel sheepish, like you do not want to be seen? | 1 | 2 | 3 | 4 | 5 |
| 4. Feel like something stinks, puts a bad taste in your mouth? | 1 | 2 | 3 | 4 | 5 |
| 5. Feel you can't stand yourself? | 1 | 2 | 3 | 4 | 5 |
| 6. Feel embarrassed when anybody sees you make a mistake? | 1 | 2 | 3 | 4 | 5 |
| 7. Feel unhappy, blue, downhearted? | 1 | 2 | 3 | 4 | 5 |
| 8. Feel surprised, like when something suddenly happens you had no idea would happen? | 1 | 2 | 3 | 4 | 5 |
| 9. Feel like somebody is a low-life, not worth the time of day? | 1 | 2 | 3 | 4 | 5 |

Office Use Only	(18)
	(19)
	(20)
	(21)
	(22)
	(23)
	(24)
	(25)
	(26)

Continued on back of this page

Since your diagnosis of cancer,
In your daily life, how often do you ...

Since your diagnosis of cancer, In your daily life, how often do you ...		Rarely	Hardly	Some- Often	Very Often	
		Ever	times			
10.	Feel shy, like you want to hide?	1	2	3	4	5
11.	Feel like what you're doing or watching is interesting?	1	2	3	4	5
12.	Feel scared, uneasy, like something might harm you?	1	2	3	4	5
13.	Feel mad at somebody?	1	2	3	4	5
14.	Feel mad at yourself?	1	2	3	4	5
15.	Feel happy?	1	2	3	4	5
16.	Feel like somebody is a "good-for-nothing"?	1	2	3	4	5
17.	Feel so interested in what you're doing, caught up in it?	1	2	3	4	5
18.	Feel amazed, like you can't believe what's happened, it was so unusual?	1	2	3	4	5
19.	Feel fearful, like you're in danger, very tense?	1	2	3	4	5
20.	Feel like screaming at somebody or banging on something?	1	2	3	4	5
21.	Feel sad and gloomy, almost like crying?	1	2	3	4	5
22.	Feel like you did something wrong?	1	2	3	4	5

_____	(27)
_____	(28)
_____	(29)
_____	(30)
_____	(31)
_____	(32)
_____	(33)
_____	(34)
_____	(35)
_____	(36)
_____	(37)
_____	(38)
_____	(39)

Patient's I.D. # _____

Since your diagnosis of cancer,
In your daily life, how often do you ...

Rarely Hardly Some- Often
Ever times

23.	Feel bashful, embarrassed?	1	2	3	4	5	— (40)
24.	Feel disgusted, like something is sickening?	1	2	3	4	5	— (41)
25.	Feel joyful, like everything is going your way?	1	2	3	4	5	— (42)
26.	Feel like people laugh at you?	1	2	3	4	5	— (43)
27.	Feel like things are so rotten they could make you sick?	1	2	3	4	5	— (44)
28.	Feel sick about yourself?	1	2	3	4	5	— (45)
29.	Feel like you are better than somebody?	1	2	3	4	5	— (46)
30.	Feel like you ought to be blamed for something?	1	2	3	4	5	— (47)
31.	Feel like you feel when something unexpected happens?	1	2	3	4	5	— (48)
32.	Feel alert, curious, kind of excited about something?	1	2	3	4	5	— (49)
33.	Feel angry, irritated, annoyed?	1	2	3	4	5	— (50)
34.	Feel discouraged, like you can't make it, nothing is going right?	1	2	3	4	5	— (51)
35.	Feel afraid, shaky, and jittery?	1	2	3	4	5	— (52)
36.	Feel like people always look at you when anything goes wrong?	1	2	3	4	5	— (53)

Form: _____ 0 _ 0 _ 8 _ (1)

Patient's I.D. # _____ (4)

Today's Date: (mm/dd/yyyy) _____ / _____ / _____ (9)

Visit: 1 = 1st follow up 2=2nd follow up
3=3rd follow up _____ (17)

Instructions: For each item, circle the number that best answers the question. Please answer every question, and not write in the grey shaded areas. In responding, consider your emotions since your diagnosis of cancer.

In your daily life, how often do you ...

- | | | | | | | |
|----|--|---|---|---|---|---|
| 1. | Feel regret, sorry about something you did? | 1 | 2 | 3 | 4 | 5 |
| 2. | Feel glad about something? | 1 | 2 | 3 | 4 | 5 |
| 3. | Feel sheepish, like you do not want to be seen? | 1 | 2 | 3 | 4 | 5 |
| 4. | Feel like something stinks, puts a bad taste in your mouth? | 1 | 2 | 3 | 4 | 5 |
| 5. | Feel you can't stand yourself? | 1 | 2 | 3 | 4 | 5 |
| 6. | Feel embarrassed when anybody sees you make a mistake? | 1 | 2 | 3 | 4 | 5 |
| 7. | Feel unhappy, blue, downhearted? | 1 | 2 | 3 | 4 | 5 |
| 8. | Feel surprised, like when something suddenly happens you had no idea would happen? | 1 | 2 | 3 | 4 | 5 |
| 9. | Feel like somebody is a low-life, not worth the time of day? | 1 | 2 | 3 | 4 | 5 |

Office Use Only

(18) _____

(19) _____

(20) _____

(21) _____

(22) _____

(23) _____

(24) _____

(25) _____

(26) _____

Continued on back of this page

DES-IV

Patient's I.D. # _____

Rarely Hardly Some- Often
Ever times

In your daily life, how often do you ...

10. Feel shy, like you want to hide? 1 2 3 4 5
11. Feel like what you're doing or watching is interesting? 1 2 3 4 5
12. Feel scared, uneasy, like something might harm you? 1 2 3 4 5
13. Feel mad at somebody? 1 2 3 4 5
14. Feel mad at yourself? 1 2 3 4 5
15. Feel happy? 1 2 3 4 5
16. Feel like somebody is a "good-for-nothing"? 1 2 3 4 5
17. Feel so interested in what you're doing, caught up in it? 1 2 3 4 5
18. Feel amazed, like you can't believe what's happened, it was so unusual? 1 2 3 4 5
19. Feel fearful, like you're in danger, very tense? 1 2 3 4 5
20. Feel like screaming at somebody or banging on something? 1 2 3 4 5
21. Feel sad and gloomy, almost like crying? 1 2 3 4 5
22. Feel like you did something wrong? 1 2 3 4 5

_____ (27)
_____ (28)
_____ (29)
_____ (30)
_____ (31)
_____ (32)
_____ (33)
_____ (34)
_____ (35)
_____ (36)
_____ (37)
_____ (38)
_____ (39)

DES-IV
Patient's I.D. # _____

Rarely Hardly Some- Often
Ever times

In your daily life, how often do you ...

23.	Feel bashful, embarrassed?	1	2	3	4	5	____ (40)
24.	Feel disgusted, like something is sickening?	1	2	3	4	5	____ (41)
25.	Feel joyful, like everything is going your way?	1	2	3	4	5	____ (42)
26.	Feel like people laugh at you?	1	2	3	4	5	____ (43)
27.	Feel like things are so rotten they could make you sick?	1	2	3	4	5	____ (44)
28.	Feel sick about yourself?	1	2	3	4	5	____ (45)
29.	Feel like you are better than somebody?	1	2	3	4	5	____ (46)
30.	Feel like you ought to be blamed for something?	1	2	3	4	5	____ (47)
31.	Feel like you feel when something unexpected happens?	1	2	3	4	5	____ (48)
32.	Feel alert, curious, kind of excited about something?	1	2	3	4	5	____ (49)
33.	Feel angry, irritated, annoyed?	1	2	3	4	5	____ (50)
34.	Feel discouraged, like you can't make it, nothing is going right?	1	2	3	4	5	____ (51)
35.	Feel afraid, shaky, and jittery?	1	2	3	4	5	____ (52)
36.	Feel like people always look at you when anything goes wrong?	1	2	3	4	5	____ (53)

Impact of Event Scale A

Form:		FOR OFFICE USE ONLY		0 0 9 (1)	
Patient's Name I.D. #				(4)	
Today's Date: (mm/dd/yyyy)				(9)	
Visit: 0=Index				(17)	

Instructions: Below is a list of comments made by people after stressful events. Please check each item, indicating how frequently these comments were true for you.

EVENT: BEING DIAGNOSED WITH CANCER

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.....	N	R	S	O
2. I avoided letting myself get upset when I thought about it or was reminded of it.....	N	R	S	O
3. I tried to remove it from my memory.....	N	R	S	O
4. I had trouble falling asleep or staying asleep because of it.	N	R	S	O
5. I had waves of strong feelings about it.....	N	R	S	O
6. I had dreams about it.....	N	R	S	O
7. I stayed away from reminders about it.	N	R	S	O
8. I felt as if it hadn't happened or it wasn't real.	N	R	S	O

FOR OFFICE USE ONLY	(18)
	(19)
	(20)
	(21)
	(22)
	(23)
	(24)
	(25)

Continued on back of this page

EVENT: BEING DIAGNOSED WITH CANCER

	Not at all	Rarely	Sometimes	Often
9. I tried not to talk about it.	N	R	S	O
10. Pictures about it popped into my mind.	N	R	S	O
11. Other things kept making me think about it.	N	R	S	O
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	N	R	S	O
13. I tried not think about it.	N	R	S	O
14. Any reminder brought back feelings about it.	N	R	S	O
15. My feelings about it were kind of numb.	N	R	S	O

FOR OFFICE USE ONLY
_____ (26)
_____ (27)
_____ (28)
_____ (29)
_____ (30)
_____ (31)
_____ (32)

8/96

Impact of Event Scale B

FOR OFFICE USE ONLY	
Form:	0 0 9 (1)
Patient's I. D. #	(4)
Today's Date: (mm/dd/yyyy)	/ / (9)
Visit: 1=1st follow up 3=3rd follow up	2=2nd follow up (17)

Instructions: Below is a list of comments made by people after stressful events. Please check each item, indicating how frequently these comments were true for you during the past seven days. If they did not occur during that time, please indicate "not at all".

EVENT: BEING DIAGNOSED WITH CANCER

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.....	N	R	S	O
2. I avoided letting myself get upset when I thought about it or was reminded of it.....	N	R	S	O
3. I tried to remove it from my memory.....	N	R	S	O
4. I had trouble falling asleep or staying asleep because of it.	N	R	S	O
5. I had waves of strong feelings about it.....	N	R	S	O
6. I had dreams about it.....	N	R	S	O
7. I stayed away from reminders about it.	N	R	S	O
8. I felt as if it hadn't happened or it wasn't real.	N	R	S	O

FOR OFFICE
USE ONLY

(18)

(19)

(20)

(21)

(22)

(23)

(24)

(25)

Continued on back of this page

Impact of Events Scale

Pateint's I. D. # _____

Page 2/2

EVENT: BEING DIAGNOSED WITH CANCER

	Not at all	Rarely	Sometimes	Often
9. I tried not to talk about it.	N	R	S	O
10. Pictures about it popped into my mind.	N	R	S	O
11. Other things kept making me think about it.	N	R	S	O
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	N	R	S	O
13. I tried not think about it.	N	R	S	O
14. Any reminder brought back feelings about it.	N	R	S	O
15. My feelings about it were kind of numb.	N	R	S	O

FOR OFFICE USE ONLY	
.....	(26)
.....	(27)
.....	(28)
.....	(29)
.....	(30)
.....	(31)
.....	(32)

Form:		FOR OFFICE USE ONLY		0	1	1	(1)
Patient's I. D. #							(4)
Today's Date: (mm/dd/yyyy)					/		(9)
Visit: 0=Index		2=2nd follow up					
1=1st follow up		3=3rd follow up					(17)

Instructions: The following questions relate to your usual sleep habits during the **past 3 days only**. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

- During the past 3 days, what time have you usually gone to bed at night? _____
- During the past 3 days, how long has it usually taken you to fall asleep each night? (in minutes) _____
- During the past 3 days, what time have you usually gotten up in the morning? _____
- During the past 3 days, how many hours of actual sleep did you get per night?
(This may be different than the number of hours you spent in bed). _____
- During the past 3 days, how would you rate your sleep overall?
 - Very good
 - Fairly good
 - Fairly bad
 - Very bad

FOR OFFICE USE ONLY	
_____	_____ (18)
_____	_____ (22)
_____	_____ (25)
_____	_____ (29)
_____	_____ (31)

Continued on back of this page

During the past 3 days how often have you had trouble sleeping because you...

None
at all

Once

Twice

Three
times or
more

6.	Cannot get to sleep within 30 minutes.	1	2	3	4	OFFICE USE ____ (32)
7.	Wake up in the middle of the night or early morning.	1	2	3	4	____ (33)
8.	Had bad dreams.	1	2	3	4	____ (34)
9.	Have pain.	1	2	3	4	____ (35)
10.	During the past 3 days, how often have you taken medicine to help you sleep? (Either prescribed or "over the counter")	1	2	3	4	____ (36)
What medications have you taken? (Include dosages if known)						

11.	During the past 3 days, how often have you had trouble staying awake while driving, eating meals, or engaging in a social activity?	1	2	3	4	____ (37)
12.	During the past 3 days, how often have you taken any medicine for nerves, anxiety, worry, or feeling blue?	1	2	3	4	____ (38)
What medications have you taken? (Include dosages if known.)						

13. How many drinks of alcohol have you had in the past 3 days?

Source: Donaldson, et al 7/95 HP

- 1 = none or only sips for religious services
- 2 = only sips (**not** for religious services)
- 3 = part or all of one drink
- 4 = 2 to 4 drinks
- 5 = 5 to 10 drinks
- 6 = 11 to 20 drinks
- 7 = more than 20 drinks

14. In the past 3 days, have you used any of the following - Marijuana/Hashish, Cocaine, Stimulants (speed), Depressants (downers), Narcotics (e.g. heroin), Hallucinogens (e.g. LSD) or Inhalants?

- 1 = Yes
- 2 = No

15. Do you currently smoke cigarettes? Have you ever considered yourself a "smoker"?

- 1 = Yes, I currently smoke cigarettes
- 2 = No, I used to smoke but I quit less than 8 weeks ago
- 3 = No, I used to smoke but I quit more than 8 weeks ago
- 4 = No, I never smoked (skip to question 18)

16. In the past week, how many days did you smoke? _____

17. How many cigarettes do you currently smoke per day? _____

18. In the past 48 hours how many cups of caffeinated coffee, tea or cola have you had? _____

OFFICE USE ONLY

____ (39)

____ (40)

____ (41)

____ (42)

____ (43)

____ (45)

FOR OFFICE USE ONLY

Form:

0 1 5 (1)

Patient's I. D. #

____ (4)

Today's Date: (mm/dd/yyyy)

____ / ____ / ____ (9)

Visit: 2=2nd follow up

3=3rd follow up

____ (17)

1. Menopausal Status

1 = Premenopausal less than or equal to 6 months since last menstrual period, no prior ovariectomy

2 = premenopausal less than or equal to 55 years of age with a previous hystserectomy, one or both ovaries intact and normal pre-menopausal FSH level

3 = Other premenopausal

4 = Postmenopausal

5 = Other

2. Surgery Description (Use most extensive surgery)

1 = Breast sparing procedure with axillary dissection

2 = Modified radical or radical mastectomy

3. Date of mastectomy or date of axillary dissection if breast sparing procedure (mm/dd/yyyy)

____ / ____ / ____ (21)

4. Estrogen receptor status

1 = Positive

2 = Negative

3 = Unknown

____ (29)

5. Progesterone receptor status

1 = Positive

2 = Negative

3 = Unknown

____ (30)

6. Pathologic Tumor Size (Centimeters)

Maximum diameter of entire lesion including both invasive and intraductal components. Use longest lesion with invasive component.

____ . ____ (31)

FOR OFFICE USE ONLY

____ (19)

____ (20)

Social Network and Support Assessment

For Office Use Only

Form:

016 (1)

Patient ID #:

____ (4)

Today's Date (mm/dd/yyyy):

____/____/____ (11)

Please answer the following questions to the best of your ability. Circle the response that applies.

1. How often does your spouse/partner make you feel loved and cared for?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

____ (19)

2. How often do you feel your spouse/partner makes too many demands on you?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

____ (20)

3. How often is your spouse/partner willing to listen when you need to talk about your worries or problems?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

____ (21)

4. How often is he/she critical of what you do?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

____ (22)

5. How often can you count on your spouse to help with daily tasks like shopping, giving you a ride, or helping you with household tasks?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

____ (23)

6. How often does your spouse give you advice or information about medical, financial, or family problems?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

____ (24)

OFFICE USE ONLY

Patient ID #: _____
SNSA - Page 2/4

7. Taking all things together, how satisfied are you with your marriage?

1. Not Applicable 2. Never 3. Rarely 4. Sometimes 5. Frequently

_____ (25)

8. How many friends and relatives, excluding your spouse do you have that you feel close to? (People you feel at ease with, can talk to about private matters, and can call on for help.)

Friends:

- 00. No close friends, does not apply
- 01. One
- 02. 2-5
- 03. 6-9
- 04. More

Relatives:

- 05. No close relatives, does not apply
- 06. One
- 07. 2-5
- 08. 6-9
- 09. More

_____ (26)

_____ (28)

9. How many of these friends and relatives live in your city or its suburbs?

Friends:

- 00. No close friends, does not apply
- 01. One
- 02. 2-5
- 03. 6-9
- 04. More

Relatives:

- 05. No close relatives, does not apply
- 06. One
- 07. 2-5
- 08. 6-9
- 09. More

_____ (30)

_____ (32)

10. How many of the friends and relatives you feel close to do you see at least once a month?

Friends:

- 00. No close friends, does not apply
- 01. One
- 02. 2-5
- 03. 6-9
- 04. More

Relatives:

- 05. No close relatives, does not apply
- 06. One
- 07. 2-5
- 08. 6-9
- 09. More

_____ (34)

_____ (36)

11. How often do your close friends and relatives make you feel loved and cared for?

Friends:

- 00. No close friends, does not apply
- 01. Never
- 02. Rarely
- 03. Sometimes
- 04. Frequently

Relatives:

- 05. No close relatives, does not apply
- 06. Never
- 07. Rarely
- 08. Sometimes
- 09. Frequently

_____ (38)

_____ (40)

Patient ID #: _____

SNSA - Page 3/4

12. How often do you feel these friends and relatives make too many demands on you?

Friends:

- 00. No close friends, does not apply
- 01. Never
- 02. Rarely
- 03. Sometimes
- 04. Frequently

Relatives:

- 05. No close relatives, does not apply
- 06. Never
- 07. Rarely
- 08. Sometimes
- 09. Frequently

_____ (42)

_____ (44)

13. How often are these friends and relatives willing to listen when you need to talk about your worries or problems?

Friends:

- 00. No close friends, does not apply
- 01. Never
- 02. Rarely
- 03. Sometimes
- 04. Frequently

Relatives:

- 05. No close relatives, does not apply
- 06. Never
- 07. Rarely
- 08. Sometimes
- 09. Frequently

_____ (46)

_____ (48)

14. How often are your close friends and relatives critical of what you do?

Friends:

- 00. No close friends, does not apply
- 01. Never
- 02. Rarely
- 03. Sometimes
- 04. Frequently

Relatives:

- 05. No close relatives, does not apply
- 06. Never
- 07. Rarely
- 08. Sometimes
- 09. Frequently

_____ (50)

_____ (52)

15. How often can you count on these people to help with daily tasks like shopping, giving you a ride or helping you with household tasks?

Friends:

- 00. No close friends, does not apply
- 01. Never
- 02. Rarely
- 03. Sometimes
- 04. Frequently

Relatives:

- 05. No close relatives, does not apply
- 06. Never
- 07. Rarely
- 08. Sometimes
- 09. Frequently

_____ (54)

_____ (56)

Patient ID #: _____

SNSA - Page 4/4

16. How often do these people give you advice or information about medical, financial, or family problems?

Friends:

- 00. No close friends, does not apply
- 01. Never
- 02. Rarely
- 03. Sometimes
- 04. Frequently

Relatives:

- 05. No close relatives, does not apply
- 06. Never
- 07. Rarely
- 08. Sometimes
- 09. Frequently

_____ (58)

_____ (60)

17. How satisfied are you with the kinds of relationships you have with your friends and relatives?

Friends:

- 00. No close friends, does not apply
- 01. Not at all satisfied
- 02. Not very satisfied
- 03. Somewhat Satisfied
- 04. Very satisfied
- 05. Completely satisfied

Relatives:

- 06. No close relatives, does not apply
- 07. Not at all satisfied
- 08. Not very Satisfied
- 09. Somewhat satisfied
- 10. Very satisfied
- 11. Completely satisfied

_____ (62)

_____ (64)

INTERVENTION INVENTORY

FOR OFFICE USE ONLY

Form: _____ 0 1 8 (1)

Patient's I.D. # _____ (4)

Today's Date: (mm/dd/yyyy) _____ / _____ / _____ (9)

Visit: 01 = 1st Intervention
02 = 2nd Intervention _____ (17)

Please do not write in shaded areas.

Please mark ONE answer for each of the following questions.

Please indicate the topics that were covered in this session.

	Yes topic was covered	No topic was not covered	Unsure if topic was covered	
1) Leader explained the purpose of the session.	1	2	3	_____ (18)
2) Practice of relaxation techniques.	1	2	3	_____ (19)
3) Definition of stress.	1	2	3	_____ (20)
4) Common responses to stress	1	2	3	_____ (21)
5) Problem-solving/coping strategies	1	2	3	_____ (22)

For each topic, circle the number that best describes the extent to which it was helpful.
If the topic was not covered, circle Not Covered (N/C).

6) Leaders' explanation of the purpose of the session. N/C _____ (23)

0-----1-----2-----3-----4-----5-----6

not at all a little bit somewhat moderately quite a bit a great deal extremely

Patient/s I.D. # _____

7) Practice of relaxation techniques. N/C

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____(24)

8) Definition of stress. N/C

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____(25)

9) Common responses to stress. N/C

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____(26)

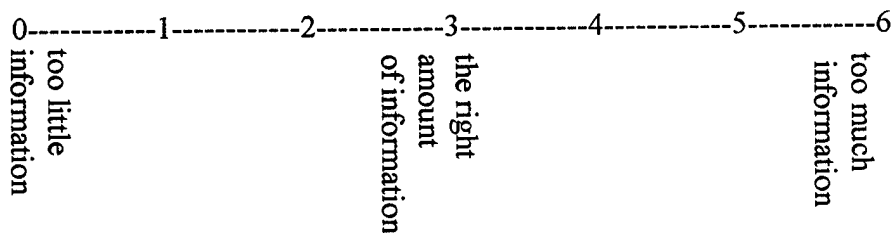
10) Problem-solving or coping strategies. N/C

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

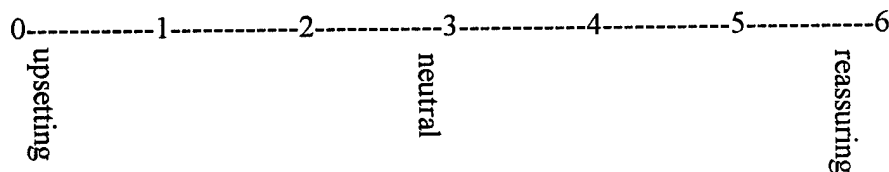
____(27)

Patient/s I.D. # _____

- (11) Circle the number that best describes your experience of the amount of information provided in this session.



- 12) Circle the number that best describes your emotional experience of this session.

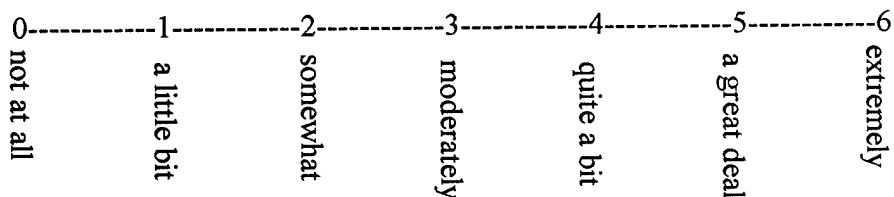


STOP HERE.

CONTINUE ONLY IF TWO OR MORE PARTICIPANTS WERE IN THIS SESSION.

Read each statement carefully and try to think of the group as a whole. Using the rating scale as a guide, circle the number of each statement that best describes the group during today's session. Group experiences can be different for different members. We are interested in learning about how you experienced this group today.

- 13) The members liked and cared about each other.



____(28)

____(29)

____(30)

Patient/s I.D. # _____

14) The members tried to understand why they do the things they do, tried to reason it out.

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____ (31)

15) The members felt what was happening was important and there was a sense of participation.

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____ (32)

16) The members challenged and confronted each other in their effort to sort things out.

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____ (33)

17) The members revealed sensitive personal information or feelings.

0-----1-----2-----3-----4-----5-----6
not at all a little bit somewhat moderately quite a bit a great deal extremely

____ (34)

A Psychosocial Workshop for Women Following a Diagnosis of Breast Cancer:

Can It Help?

A Research Study



APPENDIX 2

*Will this research affect
my medical treatment?*

*Your medical treatment will not be affected by
your decision to participate in this research
project. Nor will it be affected if you decline to
participate.*

How do I get more information?

*Heather Frazer is the Health Project
Coordinator/Clinical Technologist for this
research project. If you have any questions or
concerns, please call her at 273-2545*

*Thank you for taking the time to consider
participating in this study.*

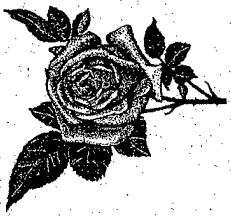
*Who are the people
doing this research?*

*The Principal Investigator is Jan Moynihan,
Ph.D. an Associate Professor of Psychiatry,
Microbiology and Immunology, and Oncology.*

*The Co-Principal Investigator is Paul
Duberstein, Ph.D., a clinical psychologist, and
Assistant Professor of Psychiatry and Oncology.*

*This research is being conducted
at the University of Rochester
and is federally funded.*

*University of Rochester
300 Crittenden Boulevard
Rochester, New York 14642
(716) 273-2545*



What is the purpose of this research study?

Women experience varying amounts of psychological distress after receiving a breast cancer diagnosis. Our study will attempt to determine if relieving distress improves immune function and psychological well-being.

How can I help?

You can help by agreeing to participate in this study. We expect that the results will be used to help women with breast cancer in the future. Your participation in this project is voluntary.

What will I be asked to do?

You will be asked to help in three ways:

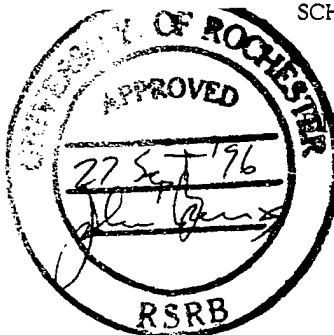
- 1. Participate in a 30 minute interview and complete a series of questionnaires about your thoughts and feelings. Some of the questionnaires can be done in your doctor's office and some at home. You will complete these forms twice before surgery and twice after surgery. All of your answers will be kept confidential.*
- 2. Allow us to draw about 2-3 tablespoons of blood from your arm each time you complete a set of questionnaires.*
- 3. Be assigned to a "counseled" or a "non-counseled" group.*

What is the "Counseled" group?

If you are assigned to the counseled group, you will attend two 90 minute workshops designed to teach relaxation and coping strategies for dealing with aspects of the illness that you might find troubling. These workshops will be held prior to your surgery, and will be led by clinical psychologists Nancy Talbot, Ph.D. and Mark Larson, Ph.D.

What is the "Non-Counseled" group?

If you are assigned to the group that does not receive counseling, you will receive medical treatment as usual. Your immune function will be compared to the counseled group to determine if our intervention will change immune response.



RSRB # 6592

WRITTEN CONSENT FORM FOR RESEARCH PARTICIPANTS

Title of Project: Effects of Psychosocial Intervention in Women following Breast Cancer Diagnosis

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You are being asked to participate in a research study designed to evaluate the effects of a psychosocial intervention on feelings of psychological well-being and the function of the immune system, which is critical for producing resistance to disease and for maintaining health. The purpose of the study is to determine if relieving psychological distress is associated with any changes in immunity. Immune function will be measured by analyzing cells in blood samples. Before agreeing to participate in this study, you will need to know the answers to the following questions.

1. What will I be asked to do?

All study participants will be asked to have a small volume of venous blood (30 cc--approximately 2-3 tablespoons) drawn from their arm and to fill out a brief questionnaire at four times during the study:

- study entry (today);
- pre-admission physical (one or two days before surgery);
- first post-surgical visit to your surgeon's office;
- 6-12 month follow-up visit.

Participants in the study will be randomly (like the toss of a coin) assigned to two groups. Members of one group will only have blood drawn and fill out the questionnaire. The other group members will be asked to participate in three intervention sessions prior to surgery, in addition to the blood draws and completion of questionnaires.

2. What is the intervention therapy?

Participants assigned to the intervention group will be asked to attend three 90 minute group therapy sessions beginning within one week of cancer diagnosis. The sessions will be held two or three days apart at the University of Rochester Medical Center in the Department of Psychiatry. These intervention sessions will be led by two trained clinical psychologists. The intervention will consist of three parts:

- learning stress reduction/relaxation techniques to help participants relieve distress
- group social support
- increasing coping skills and learning new strategies to deal with cancer diagnosis

Subject's initials _____

Witness's initials _____

3. Are there any risks?

There are no risks known to us in completing the questionnaires or participating in the intervention group.

The risk of venipuncture are small: the possibility of hematoma or slight bruising at the injection site. In this case, pressure and ice will be applied. While additional care for the bruising is highly unlikely, if necessary, emergency care at Strong Memorial Hospital will be provided at no cost to the participant. You are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. The U.S. Army requires that this institution provide such medical care when conducting research with private citizens. Other than medical care that may be provided, you will not receive any compensation for your participation in this research study; however, you should understand that this is not a waiver or release of your legal rights.

4. Are there any benefits to me?

It is not possible to predict whether any personal benefit will result from participation in this study. Research participants may find the experience rewarding.

5. Do I have to participate in this study?

Participation in this study is totally voluntary, and you are free to withdraw your consent to participate at any time without jeopardizing your present or future care in any way. There is no compensation for your participation in this study, and there is no cost to you for participation.

6. What will happen to the information gathered from this study?

The information being obtained from this study will be used for scientific purposes. Your confidentiality will be assured in all aspects of this research. If the results are published you will not be identified by name. Your study records may be reviewed by representatives of the U.S. Food and Drug Administration and the U.S. Army.

After you have read this consent form, please feel free to ask any questions that will help you understand the research better. If you have additional questions about this research, research-related injury or your rights as a research subject, you may contact Dr. Paul Duberstein at 275-6742.

My signature on this page and initials on all others indicate that I have read and understand the above, all questions have been answered to my satisfaction, and I consent to participate in the study. However, if I want to discontinue participation in this study at any time, I am free to do so without jeopardy or prejudice of normal medical care. I will be given a copy of this consent form.

Subject's Name (Print)

Subject's Signature

Date

Auditor Witness Signature

Date

The signature of the investigator below indicates that the subject has heard and understands the contents of this form, that her questions have been adequately addressed, and that she/he has verbally agreed to participate in this phase of the research study.

Investigator's Signature

Date

RSRB

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APPENDIX 4

Outline: Psychsocial Workshop

I. Opening Statement and Introductions (10 min)

Purpose of workshop

Frequency of workshop meetings; open membership

Confidentiality

Introductions

Today's agenda

"This is a workshop for women who have received a diagnosis of breast cancer and are preparing for surgery. Women are invited to attend two meetings of this workshop. Some of the women here today have attended previous meetings; for others this is their first meeting. Our purpose is to help you build on your coping and relaxation skills to manage this period in your lives. We will also be talking about common emotional responses to stressful life events.

We assume that everyone in this workshop will keep each other's confidentiality so that participants can be reassured that what they say will remain in the room."

Introduce ourselves and give credentials.

Ask participants to give their names, when they received their diagnosis, when surgery is scheduled, and how they are doing with all this.

II. Psychoeducation (35 min)

A. Experiencing Stressful Life Events.

1. Commonality of stress experience
"Everyone in this room is experiencing a stressful life event: having the diagnosis of breast cancer."
2. Defining stress
"Stress responses occur when external events challenge our coping capacities. We are thrust into a state of disequilibrium where we feel like we have lost our balance and are not in control."
3. Responses to stress (physical, feelings, thoughts, actions)
"How do we know that we are experiencing stress?" Leaders inventory on the board a list of changes in feelings, actions, thoughts and bodily responses that members generate. Leaders make a point that there are many different types of responses to stress. Individuals will tend to have certain kinds of responses - for example, more physical symptoms - rather than others. So, while stress responses can look different in different people, it's all stress.

B. Problem-Solving in Response to Stressful Life Events

1. Identify the problems.

"The first step in coping successfully with stressful life events is to identify the problems - what, specifically, is causing you to experience stress. In the next few weeks you will all be going to the hospital for surgery. What aspects of this diagnosis are particularly stressful for you?" Leaders work with participants to delineate specific problems.

2. Choose a strategy.

“The second step of effective coping or problem-solving is to choose a strategy for dealing with the problem. There are three categories of problem-solving strategies: (1) active behavioral, (2) active cognitive, and (3) avoidance.”

Leaders discuss the relative merits of these strategies.

3. Tailor the strategy.

“Let’s think in more detail about how these three broad categories of strategies can be tailored to individual problems.” Leaders work with members to examine how the three strategies could be applied to their particular problem, and what the consequences might be. If necessary to promote discussion, leaders may use a few case vignettes.

III. Relaxation Training (35 min)

Introduction

Rationale

Demonstration

Induction

Debriefing (and distribute audiotape)

IV. Closure (10 min)

Debriefing: What was this workshop meeting like for members?

Ask participants to complete a questionnaire

APPENDIX 5

BREAST CANCER SUPPORT GROUPS

Listed below are several support groups around the area dealing with issues associated with breast cancer as well as other types of cancer. These support groups are either led professionally or by a peer. In professionally led support groups, a clinician, doctor, social worker, nurse, or another health professional leads each meeting. Peer led support groups are run by someone who has personal experience with breast cancer or another type of cancer.

Breast Cancer Support Group (professionally led)

Place: Strong Memorial Hospital

Dates: Meetings once a week for six weeks (call for exact times)

Phone: 275 - 5908

*Call J.E. Giarrizzo for more info and/or to register

** This is a closed group so you must register to attend meetings **

Circle of Friends Support Group (peer led)

Place: American Cancer Society

1400 North Winton Road, Irondequoit

Dates: Meetings once a month on the third Thursday of the month (call for exact times)

Phone: 288 - 1950

Breast Cancer Support Group (professionally led)

Place: Highland Hospital's Breast Care Center in Highland Hospital's Center for Women

Time: 5:30pm - 7:00pm, every third Tuesday (call for exact dates)

Phone: 271 - 4636

Breast Cancer Support Group (professionally led)

Place: Cancer Action Inc.

225 Alexander St.

Rochester, NY 14607

Time: 7:30pm - 9:00pm, second Wednesday of each month

Phone: 423 - 9700

*Call Gail Nealon (client services director) for dates

Families Coping with Cancer (professionally led)

A support group and info for cancer patients and/ or their families and friends

Place: Cancer Action Inc.

Time: 5:30pm - 7:00 pm

Dates: Two 5-week series (call Gail Nealon for exact dates)

Phone: 423 - 9700

*This program has a fee of \$30 per person

Make Today Count (professionally led)

A support group for anyone with a cancer diagnosis

Place: Cancer Action Inc.

Time: 1:00pm - 2:30pm every Tuesday

Phone: 423 - 9700

*Contact Pat Fitzpatrick, MA (client services director) for more info

*An interview is required before your first meeting

Living with Cancer Support Group (professionally led)

A support group for people with cancer, their friends and family.

Place: The Genesee Hospital

Time: Every other Wednesday evening from 6pm - 8pm (call for exact dates)

Phone: 263 - 5348

*Call Linda Weisbeck, MS, RN (the group leader) to register for this program